REMARKS

This application has been amended in a manner that is believed to place it in condition for allowance at the time of the next Official Action.

Claims 42-58 are pending in the present application. Claims 26-41 have been cancelled. Support for new claims 42-58 may be found generally throughout the specification and in previously-pending claims 26-41.

Claim 42 recites a mixture of phospholipids comprising phosphatidylcholine and phosphatidylethanolamine and at least one of phosphatidylserine and phosphatidylinositol, wherein the phospholipids are in a ratio of phosphatidylcholine and phosphatidylethanolamine to phosphatidylserine and phosphatidylinositol of 0.5-20:1 (wt/wt). Support for this recitation may be found on page 8, lines 17-23.

Claim 55 has been drafted in a manner so as to recite a ratio for the omega-3 and omega-6 fatty acids. Support for this recitation may be found on pages 7 and 8 of the present specification.

Support for claims 57 and 58 may be found in the original claims and present specification at page 8, lines 22-23.

In the outstanding Official Action, claim 41 was rejected under 35 USC §112, first paragraph, as allegedly containing subject matter which was not described in the

specification in such a way to reasonably convey to one skilled in the relevant art that the inventors, at the time that the application was filed, had possession of the claimed invention. Applicants believe that this rejection has been obviated by the present amendment.

As noted above, claim 41 has been cancelled. New claims 42-58 have been drafted in a manner so that they are directed to omega-3 and omega-6 fatty acids. Omega-3 and omega-6 fatty acids are clearly recited in the specification and found in the original claims. Thus, it is respectfully submitted that the present disclosure conveys to one of ordinary skill in the art that when the application was filed, applicants had possession of the claimed invention.

Claims 26-40 were rejected under 35 USC §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. This rejection is respectfully traversed.

As noted above, claims 26-40 have been cancelled. New claims 42-58 have been added. Applicants believe that new claims 42-58 have been drafted in a manner so that the claimed ratios are definite to one of ordinary skill in the art.

In imposing the rejection, the Official Action alleged that claim 41 was indefinite for reciting gamma fatty acids.

However, as noted above, claims 42-58 have been drafted so that they are directed to omega-3 and omega-6 fatty acids. The claims no longer recite gamma fatty acids.

In the outstanding Official Action, claims 26, 30, 32, 35-36, 38, and 41 were rejected under 35 USC §103(a) as allegedly being unpatentable over HORROBIN, MAGGIONI and HIBINO. This rejection is respectfully traversed.

Applicants believe that the present combination of HORROBIN, MAGGIONI, and HIBINO fails to disclose or suggest the claimed invention. The claimed invention relates to a composition for the treatment of depression and/or anxiety. The composition may contain natural antioxidants, compositions of the essential fatty acids, and essential nutrients.

However, HORROBIN fails to disclose or suggest the use of the phospholipids recited in the claims for the prevention and/or treatment of depression or depression-related disorders. Indeed, HORROBIN only refers to phospholipids as a possible carrier for the fatty acid DHA. HORROBIN does not teach or mention a mixture of phospholipids comprising phosphatidylcholine and phosphatidylethanolamine and at least one of phosphatidylserine and phosphatidylinositol, wherein the phospholipids are in a ratio of phosphatidylcholine and phosphatidylethanolamine to phosphatidylserine and phosphatidylinositol of 0.5-20:1 (wt/wt).

In an effort to remedy the deficiencies of HORROBIN, the outstanding Official Action cites to MAGGIONI. However, while MAGGIONI may suggest the use of phosphatidylserine in treating depressive disorders, MAGGIONI does not teach the use of the additional claimed phospholipids or the claimed ratio.

As to the HIBINO publication, HIBINO teaches administering a compound having a choline skeleton to treat sleep disorders. HIBINO refers to the composition as a sleep rhythm improver. While HIBINO mentions depression, this depression is not related to a mood-related depression. Rather, the depression is a result of a sleep disorder. The active agent used by HIBINO is choline. However, choline may or may not be in the form of a phopholipid. As a result, HIBINO fails to disclose or suggest a specific role for phospholipids in the treatment of depression. Moreover, HIBINO fails to disclose the claimed mixture of phospholipids.

The claimed invention is also directed to a method for the prevention and/or treatment of depression or depression-related disorders, wherein long chain polyunsaturated fatty acids, and the amounts and ratios of the long chain polyunsaturated fatty acids are specifically recited (see claim 55). Applicants submit that none of the publications provide the necessary motivation to one of ordinary skill in the art to modify and combine the teachings of the cited publications to

obtain the claimed invention. Indeed, there is no recognition of the recited long chain polyunsaturated fatty acids or their recited amounts.

The claimed invention is also directed to a composition wherein vitamin D3 is in an amount between 4 and 40 µg per day (see claim 57). While HORROBIN mentions vitamin D3, HORROBIN only refers to vitamin D in a general context that covers all vitamins and essential minerals (Example 3). There is no teaching to administer vitamin D3. Moreover, there is no suggestion that vitamin D3 is present in an amount between 4 and 40 µg per day. Thus, it is believed that the proposed combination of publications fails to disclose or suggest the subject matter of claim 57.

In imposing the rejection, the outstanding Official Action also alleged that it would be obvious to optimize the amounts and/or ratios of the claimed components as a matter of routine experimentation. However, as the Examiner is aware, a particular parameter must first be recognized as a result-effective variable, i.e., a variable which uses a recognized result, before the determination of the optimum or workable ranges of the variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). As none of the cited publications teach or characterize the claimed amounts and/or ratios as capable of being optimized,

applicants believe that one of ordinary skill in the art would have lacked the motivation to combine each of the claimed components in their recited amounts and ratios. Indeed, none of the publications even refer to or teach that the claimed components can be placed together in a ratio as claimed that would be beneficial for the prevention and/or treatment of depression or depression-related disorders.

As a result, applicants believe that the proposed combination fails to disclose or suggest the claimed invention.

Claims 26-27, 29-30, 32-33, 35-38, and 41 were rejected under 35 USC §103(a) as allegedly being unpatentable over HORROBIN, MAGGIONI, HIBINO and FUGH-BERMAN.

Applicants respectfully submit that the FUGH-BERMAN publication fails to remedy the deficiencies of HORROBIN, MAGGIONI, and HIBINO. Indeed, the FUGH-BERMAN publication fails to disclose or suggest the claimed amounts and ratios recited in the present invention.

Thus, applicants believe that the proposed combination of HORROBIN, MAGGIONI, HIBINO, and FUGH-BERMAN fails to render obvious the claimed invention.

Claims 26, 29, 30, 32-36, 38, and 41 were rejected under 35 USC §103(a) as allegedly being unpatentable over HORROBIN, MAGGIONI, HIBINO, and POLLACK et al. This rejection is respectfully traversed.

Applicants believe that the POLLACK et al. publication fails to remedy the deficiencies of HORROBIN, MAGGIONI, and HIBINO. POLLACK et al. is directed to a composition for treating physiological disorders pertaining to the regulation of the neurotransmitter serotonin. However, applicants respectfully submit that POLLACK et al. fail to teach a method for treating depression by administering to a patient in need thereof a composition containing the claimed ingredients, amounts and ratios. Indeed, applicants believe that POLLACK et al. fail to disclose or suggest a method for treating depression by administering to a patient in need thereof a composition comprising the claimed long chain polyunsaturated fatty acids, the claimed phospholipids, and the claimed related compound.

As a result, it is believed that the proposed combination of HORROBIN, MAGGIONI, HIBINO, and POLLACK et al. fails to render obvious the claimed invention.

Claims 26, 30, 32, 35-36, 38, and 41 were rejected under 35 USC §103(a) as allegedly being unpatentable over HORROBIN, MAGGIONI, HIBINO, and TAKEDA. This rejection is respectfully traversed.

TAKEDA teaches a depressive symptom improvement agent. The agent comprises carnitine and vitamin B1. The composition relates to an agent designed to provide an invigorating effect to one suffering from depression related stress and fatigue.

However, the publication is related to a stimulant. Moreover, the publication does not teach the claimed components, amounts or ratios. As a result, it is believed that the TAKEDA publication fails to remedy the deficiencies of HORROBIN, MAGGIONI, and HIBINO.

As a result, applicants believe that the proposed combination fails to render obvious the claimed invention.

As the claims now in the case clearly bring out these distinctions with ample particularity, it is believed that they are all patentable and reconsideration and allowance are respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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